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EXAMINER

GUZO, DAVID

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1636

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Detailed Action

Claims 91-92, 100-101, 112 and 114 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/29/05.

Applicants request rejoinder of withdrawn process claims that depend from or otherwise include all of the limitations of the allowable product claims. Rejoinder is not applicable at this point because no product claims are in condition for allowance.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 59-61, 63-90, 93-99, 102, 104-111, 113 and 115-116 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46, 49-90, 93-99 and 101-104 of copending Application No. 11/535,003. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a polynucleotide comprising, in operable linkage: (a) a fusion gene comprising a first selectable gene and an amplifiable second selectable gene; (b) a selected sequence encoding a desired product; and (c) a promoter, wherein the first selectable gene is not an amplifiable selectable gene (see especially claim 62 of the '003 application) as well as host cells comprising said polynucleotides and kits comprising said polynucleotides. All of the instant claims recite that the polynucleotide comprises a fusion gene between a first selectable gene and an amplifiable second selectable gene wherein the first selectable gene is not an amplifiable selectable gene as well as a sequence encoding a desired product and a promoter. The claims of the '003 application recite the same components as instantly claimed (see claim 1 of the '003 application). Claim 8 of the '003 application recites a fusion gene between the first and second markers and Claim 62 of the copending application recites that the first selectable gene is not amplifiable. All other limitations of the instant claims are likewise recited in the '003 claims. The instant claims are therefore obvious over the claims in the '003 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-61, 63-90, 93-99, 102, 104-111, 113 and 115-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record in the previous Office Action (mailed 9/26/06) and for reasons outlined below. The new points of arguments included here are necessitated by applicants' amendment.

Applicants traverse this rejection by amending the claims to recite: "wherein the first selectable gene is not an amplifiable selectable gene" and asserting that "amplifiable selectable gene" is defined in the specification at pages 12-13. Applicants submit that the meaning of "amplifiable selectable gene" is clear when read in light of the specification.

Applicant's arguments filed 3/22/07 have been fully considered but they are not persuasive. Applicants define an "amplifiable selectable gene" on p. 12 of the instant specification as follows:

An "amplifiable selectable gene" has the properties of a selectable marker gene as defined above, but additionally can be amplified (i.e., additional copies of the gene are generated which survive in intrachromosomal or extrachromosomal form) under appropriate conditions. The amplifiable selectable gene usually encodes an enzyme which is required for growth of eukaryotic cells under those conditions. For example, the amplifiable selectable gene may encode DHFR (dihydrofolate reductase) which gene is amplified when a host cell transfected therewith is grown in the presence of the selective agent, methotrexate (Mtx). The exemplary selectable genes in Table 1 below are also amplifiable selectable genes. An example of a selectable gene which is

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generally not considered to be an amplifiable gene is the neomycin resistance gene (Cepko et al, supra).

The instant definition of an “amplifiable selectable gene” would appear to include any selectable marker because any given selectable marker gene can be amplified (i.e., additional copies of the gene are generated which survive in intrachromosomal or extrachromosomal form) by inclusion on a given replicon or by being operably linked to an amplifiable gene such as the dhfr gene. It is unclear what characteristics a selectable gene would have so as to be considered a selectable gene which is **not amplifiable**. This issue is made even more confusing in that applicants recite an example of a selectable gene which applicants indicate is not generally considered to be amplifiable (the neomycin resistance gene (neo)); however, the prior art (see for example, US Patent 5,919,635, column 9, lines 11-33) lists the neomycin resistance gene as a **preferred amplifiable genetic marker**.

Any rejections not repeated in this Office Action are withdrawn.

No Claims are allowed.

It is noted that this Office Action is made Final even though it contains a new ground of rejection under Obviousness Type Double Patenting over newly filed application 11/535,003 (filed 9/25/06). The 11/535,003 application was filed one day prior to the mailing of the previous Office Action (9/26/06) and was not accessible to the examiner at the time the previous Office Action was prepared. Applicants' filing of the new application and its unavailability to the examiner at the time the previous Office

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Action was prepared necessitated the new ground of rejection under Obviousness type Double Patenting and the Finality of this Office Action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
May 28, 2007


DAVID GUZO
PRIMARY EXAMINER